

Message Text

UNCLASSIFIED

PAGE 01 STATE 202528
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-09 COME-00 EB-08 /036 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/NE: DGOODMAN(INFO)

-----031996 102021Z /40

P 102009Z AUG 78
FM SECSTATE WASHDC
TO AMEMBASSY LONDON PRIORITY

UNCLAS STATE 202528

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, UK

SUBJECT: FIRM INITIATED RECALL OF MEDICAL DEVICE
(RECALL T-129-8)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED - IMV MANIFOLD - INTERMITTENT MANDATORY
VENTILATION MANIFOLD FOR DISPOSABLE (SINGLE PATIENT) USE.
TWO PACKAGING CONFIGURATIONS: 1. BASIC IMV MANIFOLD
(CATALOG NO. 396033) 2. IMV MANIFOLD WITH REBREATHING
BAG, TUBING AND NIPPLE (CATALOG NO. 396140). PRODUCTS
ARE PRESCRIPTION PRODUCTS. USE: THE IMV MANIFOLD ALLOWS
THE PATIENT TO BREATHE INTERMITTENTLY WHILE BEING VENTILATED
BY MACHINE.

P

2. PRODUCT IDENTIFICATION: IMV MANIFOLD CATALOG 396003
CODE 88132 (PACKAGED IN CASES OF 50). IMV MANIFOLD CATALOG
396140 CODE 88133 (PACKAGED IN CASES OF 12). BOTH ARE
LABELED AS BEING MANUFACTURED BY OEM MEDICAL INC., EDISON,
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 202528

NJ. LABEL LISTS BOTH CATALOG NUMBER AND CODE (LOT NUMBER.
NO PRIVATE LABELS).

3. MANUFACTURER/RECALLING FIRM: OEM MEDICAL INC.,
29 MERIDIAN RD, EDISON, NJ 08817. COMPONENT VALVE
MANUFACTURER: DEBSAN PLASTICS INC., 628 WEST FIRST AVE.,
ROSELLE, NJ 07203.

4. REASON FOR RECALL: MALFUNCTIONING ONE WAY VALVE - THE FIRM RECEIVED COMPLAINTS ALLEGING THAT THE ONE WAY VALVE IN THE MANIFOLD WAS STICKING WHICH WOULD NOT ALLOW THE PROPER SETUP OF THE VENTILATOR MACHINE WITH WHICH THE DEVICE IS USED. IF USED, THE MALFUNCTION WOULD CAUSE AN INCREASE IN THE BLOOD CARBON DIOXIDE LEVEL OF THE PATIENT. DURING VALVE MALFUNCTION THE CARBON DIOXIDE BLOOD LEVEL IN A PATIENT WAS OBSERVED TO BE AT 60MM MERCURY; AND DROP TO 35MM MERCURY AFTER 30 MINUTES OF NORMAL VALVE OPERATION (FOLLOWING CORRECTION OF THE STUCK VALVE). NO DEATHS OR INJURIES WERE REPORTED TO THE FIRM.

5. FOLLOW-UP INVESTIGATION (2/20/78) BY THE FIRM IDENTIFIED THE PROBLEM TO BE THAT THE 2 "T" SHAPED PIECES IN THE DEVICE COULD BE OVERINSERTED INTO THE MANIFOLD CONTAINING THE VALVE AND CAUSE OBSTRUCTION TO THE OPENING OF THE VALVE. THE FIRM'S PRESIDENT DETERMINED THAT THE PROBLEM WAS CAUSED BY THE USE OF A NEW MOLD TOOL BY A COMPONENT SUPPLIER WHICH HAD A SLIGHTLY ENLARGED INSIDE DIAMETER WHICH WOULD ALLOW INSERTION OF THE "T" SHAPED PIECE.

6. FIRM INITIATED RECALL ON 2/2/78. BUREAU OF MEDICAL DEVICES DISAPPROVED FIRM'S INITIAL RECALL ACTION. THE BASIS FOR THE DISAPPROVAL WAS THAT THE METHOD OF NOTIFICATION DID NOT PROVIDE ADEQUATE INSTRUCTIONS TO ALL USER
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 202528

CUSTOMERS OF THE DEVICE OR ASSURANCE THAT THE FIRM RETAINED RECORDS OF RESPONSE AND RETURNS TO DETERMINE THE EFFECTIVENESS OF THE ACTION. BUREAU EVALUATION CLASSIFICATION WAS THAT THE MALFUNCTION CONDITION PRESENTS A HAZARD OF POTENTIALLY SERIOUS CONSEQUENCES OCCURRING TO A PATIENT UNDERGOING RESPIRATORY THERAPY DUE TO OBSTRUCTION OR PARTIAL OBSTRUCTION OF THE PATIENTS AIRWAY IF NOT IMMEDIATELY DISCOVERED.

7. IN ADDITION THE PRODUCT IS CONSIDERED MISBRANDED IN THAT THE LABELING FAILS TO BEAR ADEQUATE DIRECTIONS FOR USE TO ASSURE PROPER ASSEMBLY OF THE ONE-WAY VALVE IN THE RESPIRATORY AIRWAY SYSTEM. ON 6/2/78 FDA ADVISED THE RECALLING FIRM OF THE HEALTH HAZARD AND NEED FOR THE RECALL LETTER NOTIFICATION METHOD. FIRM THEN MAILED ACCEPTABLE RECALL LETTERS ON 6/14, 6/15/78.

8. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF THEY HAVE BEEN ADVISED OF RECALL AND DISPOSITION OF DEVICES BOTH IN STOCK AND DISTRIBUTED. ANY QUESTIONS CONSIGNEE MAY HAVE SHOULD BE DIRECTED TO U.S. FIRM.

9. CONSIGNEE BLEASE MEDICAL EQUIPMENT LTD., DEANSWAY,
CHESAM, BUCKS, ENGLAND HP 52 NX VANCE

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 10 aug 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE202528
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780328-0120
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780877/aaaacmfv.tel
Line Count: 119
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: cfbe5b65-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1776025
Secure: OPEN
Status: NATIVE
Subject: FIRM INITIATED RECALL OF MEDICAL DEVICE (RECALL T-129-8)
TAGS: OGEN, ETRD, EIND, TBIO, UK
To: LONDON
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/cfbe5b65-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014